

REMARKS

With this Response, claims 7, 8, 34, 44, 47-50, 52-54 and 75 are canceled. Claims 6, 9, 11, 14, 18, 55 and 58 are amended. As such, claims 6, 9-33, 35-43, 45, 46, 51, and 55-74 are currently pending. The amendments find support in the specification and are discussed in the relevant sections below. No new matter is added.

Objection To The Specification:

The Final Action of May 20, 2005 stated:

Although the use of trademarks is permissible in patent applications, the proprietary nature of marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. See page 18, line 15. Correction is requested. (May 20, 2005 Final Action; Page 2).

With this Response, Applicant has amended the specification in order to overcome the above-identified objection.

Claims Rejected Under 35 U.S.C. §112:

The May 20, 2005 rejected claims 34 and 44 under 35 U.S.C. §112, stating:

Claims 34 and 44 contains the trademark/trade names SNOMED® and Spotfire™...In the present case, the trademark/tradename is used to identify/describe a specific type of computer code and, accordingly, the identification/description is indefinite. (May 20, 2005 Final Action; Page 3).

With this Response, claims 34 and 44 are canceled. As such, the above-identified rejection is obviated.

Claims Rejected Under 35 U.S.C. §102:

The May 20, 2005 Final Action rejected claims 6-17, 19-33, 37-42, 45, 46, and 51-74 under 35 U.S.C. §102 as being anticipated by U.S. 6,847,897 to Bassett et al.. With this Response, Applicant has incorporated dependent claim 7 and dependent claim 8 into independent claim 6 (additional claim amendments were made to account for dependency changes due to the incorporation of claims 7 and 8 into claim 6). With these amendments, the claimed invention is limited to a microarray comprising tissue samples; in addition, the specimen-linked database

links data regarding previously analyzed tissue samples and compares the previously stored information to the tissue samples of the tissue microarray. In contrast, the Bassett et al. reference merely discloses a database for correlating data from a DNA/RNA microarray (not a tissue microarray). As such, the types of information analyzed in the Bassett et al. reference is limited to hybridization data, amplification data, detection of biomarkers, and other DNA/RNA related data. Bassett et al. discloses extracting DNA or RNA from a tissue sample in order to array the DNA/RNA samples (see Bassett et al., Col. 10, Lines 32-36); however, the Bassett et al. patent does not disclose, teach or suggest the use of tissue arrays (arrays of tissue samples-not arrays of DNA/RNA) to be used in combination with a specimen-linked database to analyze such features as morphology of tissue samples, phenotype data related to each sample, visual analysis of each sample, etc. The use of tissue samples provides for the ability to collect and analyze a wide spectrum of information that is not possible with the use of merely arraying DNA/RNA samples. As such, Applicant respectfully requests withdrawal of the above-identified rejections under 35 U.S.C. §102(b).

The Bassett et al. patent discloses a system, method, and computer program for enhanced computer-aided analysis of biological response data. More specifically, Bassett et al. discloses a database for analyzing a biological array. In discussing arrays, Bassett et al. discloses:

5.2.2.1. Microarrays Generally

In a particularly preferred embodiment, **measurement of the transcriptional state are made by hybridization to microarrays of probes consisting of a solid phase, on the surface of which are immobilized a population of polynucleotides, such as a population of DNA or DNA mimics, or, alternatively, a population of RNA.** Specifically, a microarray is an array of less than 6.25 cm² in size. Microarrays can be employed, e.g., for analyzing the transcriptional state of a cell, such as the transcriptional states of cells exposed to graded levels of a drug of interest.

In preferred embodiments, a microarray comprises a surface with an ordered array of binding (e.g., hybridization) sites for products of many of the genes in the genome of a cell or organism, preferably most or almost all of the genes. Microarrays can be made in a number of ways, of which several are described below. However produced, microarrays share certain characteristics: The arrays are reproducible, allowing multiple

copies of a given array to be produced and easily compared with each other. Preferably, the microarrays are small, usually smaller than 5 cm², and they are made from materials that are stable under binding (e.g., nucleic acid hybridization) conditions. **Preferably, a given binding site or unique set of binding sites in the microarray will specifically bind (e.g., hybridize) to the product of a single gene in a cell (e.g., to a specific mRNA, or to a specific cDNA derived therefrom).** However, as discussed supra, in general other, related or similar sequences will cross hybridize to a given binding site. Although there may be more than one physical binding site per specific RNA or DNA, for the sake of clarity the discussion below will assume that there is a single, completely complementary binding site.

The microarrays of the present invention include one or more test probes, each of which has a polynucleotide sequence that is complementary to a subsequence of RNA or DNA to be detected. Each probe preferably has a different nucleic acid sequence. The position of each probe on the solid surface is preferably known. In one embodiment, the microarray is a high density array, preferably having a density greater than about 60 different probes per 1 cm². In one embodiment, the microarray is an array (i.e., a matrix) in which each position represents a discrete binding site for a product encoded by a gene (i.e., an mRNA or a cDNA derived therefrom), and in which binding sites are present for products of most or almost all of the genes in the organism's genome. For example, the binding site can be a DNA or RNA analogue to which a particular RNA can specifically hybridize. The DNA or RNA analogue can be, e.g., a synthetic oligomer, a full-length cDNA, a less-than full length cDNA, or a gene fragment.

Although in a preferred embodiment the microarray contains binding sites for products of all or almost all genes in the target organism's genome, such comprehensiveness is not necessarily required. Usually the microarray will have binding sites corresponding to at least about 50% of the genes in the genome, often to about 75%, more often to at least about 85%, even more often to about 90%, and still more often to at least about 99%...(Bassett et al.; Col 38, Lines 1-59)(Emphasis added).

As such, Bassett et al. is merely disclosing a microarray wherein each sample of the microarray is a DNA/RNA sample. Next, various probes are placed into communication with the samples in order to determine hybridization patterns. Next, the data is sent to a database for analysis.

The Bassett et al. patent does not disclose the use of a tissue microarray. As such, the Bassett et al. patent does not disclose a "tissue information system, comprising a specimen-

linked database comprising information about at least one tissue microarray identified by an identifier wherein the tissue microarray comprises samples from a patient; said tissue microarray comprises a plurality of sublocations, each sublocation identifiable by coordinates wherein after said user has inputted said identifier, the system displays an interface on said display of said user device, said interface providing a plurality of selectable coordinates corresponding to the coordinates on said tissue microarray, wherein selection of coordinates causes the system to display information about a tissue sample at the sublocation identified by said coordinates. As such, Applicant respectfully requests reconsideration and allowance of pending claims 6, 9-33, 35-43, 45, 46, 51, and 55-74.

Claims Rejected Under 35 U.S.C. §103:

The May 20, 2005 Final Action rejected claim 6, 18 and 36 under 35 U.S.C. §103(a) as being unpatentable over the Bassett et al. patent as applied to claim 6 and 7 above, and further in view of Moore et al. (Arch Pathol Lab Med. (1996) Vol. 120(8), pages 782-785).

The Moore et al. reference discloses an autopsy subdatabase (which is not disclosed in the Bassett et al. reference). However, the Moore et al. reference does not cure the above-discussed deficiency of the Bassett et al. reference; more specifically, the Moore et al. reference does not disclose a tissue microarray wherein said tissue microarray comprises a plurality of sublocations, each sublocation identifiable by coordinates wherein after said user has inputted said identifier, the system displays an interface on said display of said user device, said interface providing a plurality of selectable coordinates corresponding to the coordinates on said tissue microarray, wherein selection of coordinates causes the system to display information about a tissue sample at the sublocation identified by said coordinates. As such, Applicant respectfully request reconsideration and allows of claims 6, 18 and 36.

Next, the Office Action rejected claims 6, 34 and 35 under 35 U.S.C. §103(a) as being unpatentable over the Bassett et al. reference as applied to claim 6 above, and further in view of Bruijn et al (Medical Informatics Europe '96, J. Brender et al. eds., pages 198-202)..

The Bruijn et al. reference discloses the use of SNOMED for medical coding systems. However, the Bruijn et al. reference does not cure the above-discussed deficiency of the Bassett et al. reference; more specifically, the Bruijn et al. reference does not discloses a tissue microarray wherein said tissue microarray comprises a plurality of sublocations, each sublocation identifiable by coordinates wherein after said user has inputted said identifier, the system displays an interface on said display of said user device, said interface providing a plurality of selectable coordinates corresponding to the coordinates on said tissue microarray, wherein selection of coordinates causes the system to display information about a tissue sample at the sublocation identified by said coordinates. As such, Applicant respectfully request reconsideration and allows of claims 6 and 35.

Further, the Office Action rejected claims 6, 43 and 44 under 35 U.S.C. §103(a) as being unpatentable over the Bassett et al. reference as applied to claims 6 and 43 above, and further in view of Ahlberg (SIGMOND Record (1996) Vol. 25, No. 4, pages 25-29).

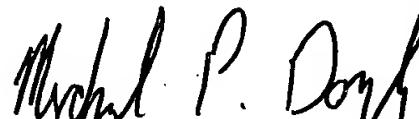
The Ahlberg et al. reference discloses the use of Spotfire™ as a database exploration system based upon interactive information visualization, dynamic queries, brushing, and linking, and other interactive graphic techniques. However, the Ahlberg reference does not cure the above-discussed deficiency of the Bassett et al. reference; more specifically, the Ahlberg reference does not discloses a tissue microarray wherein said tissue microarray comprises a plurality of sublocations, each sublocation identifiable by coordinates wherein after said user has inputted said identifier, the system displays an interface on said display of said user device, said interface providing a plurality of selectable coordinates corresponding to the coordinates on said tissue microarray, wherein selection of coordinates causes the system to display information about a tissue sample at the sublocation identified by said coordinates. As such, Applicant respectfully request reconsideration and allows of claims 6 and 43.

In summary, the Applicant has amended the sole independent claim, claim 6, by incorporating dependent claim 7 and dependent claim 8 into claim 6. The amendments were made for the purpose of distinguishing the Applicant's claimed invention over the Bassett et al. patent. More specifically, the amendments further illustrate a novel aspect of Applicant's

invention--the ability to utilize a tissue microarray linked to a database. A plurality of information may be obtained from a tissue sample which may not be obtained from a DNA/RNA sample. Since the Bassett et al. patent merely discloses the analysis of data obtained from DNA/RNA microarrays, Applicant believes the present amendments clearly render pending claims 6, 9-33, 35-43, 45, 46, 51, and 55-74 patentable over the various rejections discussed above. As such, Applicant respectfully requests reconsideration and allowance of pending claims 6, 9-33, 35-43, 45, 46, 51, and 55-74.

Applicant submits that in view of the foregoing remarks, all issues relevant to patentability raised in the Office Action have been addressed. Applicants respectfully request the withdrawal of rejections over the claims of the present invention.

Respectfully submitted,



Name: Michael P. Doyle
Registration No.: 49,052
Customer No.: 29932
Palmer & Dodge LLP
111 Huntington Avenue
Boston, MA 02199-7613
Tel.: (617) 239-0100

Date: July 20, 2005